MICROPARTICLES

This application is a continuation of US Patent application Serial No. 09/970,793 filed 10/05/2001, now US Patent No. 6,706,288.

TECHNICAL FIELD

The present invention lies within the field of galenic formulations for the administration of biologically active substances, more precisely microparticles for controlled release intended for parenteral administration of biologically active substances, especially drugs. More specifically, it relates to a novel production process for such particles containing a biologically active substance and to novel particles for controlled release obtainable thereby.

BACKGROUND TO THE INVENTION

Many drugs have to be administered by injection, since they are either subjected to degradation or are insufficiently absorbed when they are given, for example, orally or nasally or by the rectal route. A drug preparation intended for parenteral use has to meet a number of requirements in order to be approved by the regulatory authorities for use on humans. It must therefore be biocompatible and biodegradable and all used substances and their degradation products must be non-toxic. In addition, particulate drugs intended for injection have to be small enough to pass through the injection needle, which preferably means that they should be smaller than 200 μm. The drug should not be degraded in the preparation to any great extent during production or storage thereof or after administration and should be released in a biologically active form with reproducible kinetics.

One class of polymers which meets the requirements of biocompatibility and biodegradation into harmless end products is the linear polyesters based on lactic acid,